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No. 92-1979

IN THE
Supreme Court of the United States
OCTOBER TERM, 1993

JANE KING,
Petitioner,

v.

COLLAGEN CORPORATION,
Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the First Circuit

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BRIEF FOR THE RESPONDENT IN OPPOSITION

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August 1993

WILSON - EPES PRINTING CO., INC. - 789-0096 - WASHINGTON, D.C. 20001

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21 pp

QUESTION PRESENTED

Whether the Medical Device Amendments of 1976—which expressly preempt state requirements relating to safety or effectiveness that are different from or in addition to federal requirements—bar state tort claims against the manufacturer of a medical device whose design and labeling met the specific requirements imposed by the Food and Drug Administration as conditions of premarket approval.

CORPORATE AFFILIATES

Pursuant to Rule 29.1, the following is a list of all parent companies and subsidiaries (except wholly owned subsidiaries) of respondent Collagen Corporation: Target Therapeutics, Inc., CollOptics, Inc., Prograft Medical, Inc., and LipoMatrix, Inc.

TABLE OF CONTENTS

	Page
STATEMENT OF THE CASE	1
REASONS FOR DENYING THE PETITION	5
CONCLUSION	15

TABLE OF AUTHORITIES

CASES: Page

Arkansas-Platte & Gulf v. Van Waters & Rogers, 981 F.2d 1177 (10th Cir. 1993), *pet. for cert. pending*, No. 92-1784 (filed May 10, 1993) 7
Berger v. Personal Products, Inc., 797 P.2d 1148 (Wash. 1990), *cert. denied*, 111 S. Ct. 1584 (1991) 10
Cipollone v. Liggett Group, Inc., 112 S. Ct. 2608 (1992) ..... *passim*
Florida ex rel. Broward County v. Eli Lilly & Co., 329 F. Supp. 364 (S.D. Fla. 1971) 10
Hurley v. Lederle Laboratories, 863 F.2d 1173 (5th Cir. 1988) 11
Larsen v. Pacesetter Systems, Inc., 837 P.2d 1273 (Haw. 1992) 11, 12
Merrell Dow Pharmaceuticals Inc. v. Thompson, 478 U.S. 804 (1986) 14
Moore v. Kimberly-Clark Corp., 867 F.2d 243, 246 (5th Cir. 1989) 10
New Jersey Guild of Hearing Aid Dispensers v. Long, 384 A.2d 795 (N.J. 1978) 11
Orthopedic Equipment Co. v. Eutsler, 276 F.2d 455 (4th Cir. 1960) 14
Papas v. Upjohn Co., 985 F.2d 516 (11th Cir. 1993) 7
Slater v. Optical Radiation Corp., 961 F.2d 1330 (7th Cir. 1992), *cert. denied*, No. 92-303 (October 13, 1992) 6, 10, 12, 14
Smith v. Pingree, 651 F.2d 1021 (5th Cir. Unit B 1981) 11
Stamps v. Collagen Corp., 984 F.2d 1416 (5th Cir. 1993), *pet. for cert. pending*, No. 98-1989 (filed June 13, 1993) ..... *passim*
Stanton v. Astra Pharmaceutical Products, Inc., 718 F.2d 553 (3d Cir. 1983) 14

STATUTES:

21 U.S.C. § 351(f)(1) 2
21 U.S.C. § 360c 2
21 U.S.C. § 360e 2, 8

TABLE OF AUTHORITIES—Continued

	Page
21 U.S.C. § 360e(b)	11
21 U.S.C. § 360e(c) (1)	8
21 U.S.C. § 360i	3
21 U.S.C. § 360k	*passim*
42 U.S.C. § 262	11
CODE OF FEDERAL REGULATIONS:	
21 C.F.R. § 10.85(k)	13
21 C.F.R. § 801.97	12
21 C.F.R. § 808.1(b)	11-13
21 C.F.R. § 808.1(d)	8, 12
21 C.F.R. § 808.1(d) (6) (ii)	13
21 C.F.R. pt. 803	3
21 C.F.R. § 814.80	3
FEDERAL REGISTER:	
43 Fed. Reg. 18661 (May 2, 1978)	8
45 Fed. Reg. 67321 (October 10, 1980)	9
46 Fed. Reg. 46394 (September 18, 1981)	2
OTHER:	
Mass. Gen. L. ch. 231, § 85J	3

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BRIEF FOR THE RESPONDENT IN OPPOSITION

STATEMENT OF THE CASE

Petitioner Jane King filed this state-law tort action against respondent Collagen Corporation ("Collagen") in Massachusetts superior court in 1990. Collagen removed the case to the United States District Court for the District of Massachusetts on the basis of diversity of citizenship. The district court granted summary judgment in favor of Collagen on the ground that petitioner's claims were expressly preempted under section 521 of the Federal Food, Drug, and Cosmetic Act ("FD&C Act"), 21 U.S.C. § 360k, as added by the Medical Device Amendments of 1976. Pet. App. 22a-23a. The court of appeals affirmed. *Id.* at 1a-22a.

Zyderm.® Collagen manufactures and distributes Zyderm Collagen Implant (injectable bovine collagen), a prescription medical device used to correct human skin deformities. On April 30, 1980, after years of research, development, and clinical testing, Collagen submitted an application for premarket approval to the United States Food and Drug Administration ("FDA"). More than one year later, after an exhaustive review of the evidence concerning Zyderm's safety and effectiveness, FDA approved the application. 46 Fed. Reg. 46394 (September 18, 1981) (concluding that Zyderm is "safe and effective for use as recommended in the submitted labeling").

Requirements imposed by FDA. Zyderm is regulated by FDA as a "class III" medical device, a category of devices subject to comprehensive FDA requirements governing all aspects of their design and labeling and requiring FDA approval prior to marketing. *See* 21 U.S.C. § 360e. The agency's requirements for class III devices are the most sweeping and stringent of all those imposed under the device classification scheme. *See* 21 U.S.C. § 360c. A class III device such as Zyderm can be marketed only pursuant to a license granted by FDA, which imposes specific requirements governing its manufacture and labeling. (Class I devices, such as bandages, and class II devices, such as tampons, are not subject to the same premarket approval process. Instead, manufacturers of those devices need comply only with general regulations and, in some cases, requirements applicable to specific aspects of the device.)

FDA's approval of Collagen's premarket approval application ("PMA") for Zyderm created a private license permitting the manufacture and sale of the device only in accordance with the design and labeling approved by FDA through the PMA process. Any deviation from the conditions for approval of a PMA would be a *per se* violation of the FD&C Act. 21 U.S.C. § 351(f)(1). "A device may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent

with any conditions to approval specified in the PMA approval order for the device." 21 C.F.R. § 814.80. Thus, through premarket approval, FDA establishes detailed requirements regarding the design and labeling of a class III device in advance of sale.

Even after approval, manufacturers of such devices are subject to comprehensive recordkeeping and reporting obligations to ensure that they obtain and report to FDA the most up-to-date information bearing on the safety and effectiveness of a marketed medical device. 21 U.S.C. § 360i; 21 C.F.R. pt. 803. The agency has broad authority to withdraw approval of a class III device, and it often directs manufacturers to add or modify labeling for a device to take into account new information about side effects. For example, FDA originally approved labeling for Zyderm to contraindicate patients who had a personal or immediate family history of autoimmune disease; in 1983, FDA approved a labeling revision to contraindicate only those patients with a personal history of the disease; and in 1991 FDA approved deletion of the contraindication in favor of a warning that some patients had reported autoimmune reactions but that no causal connection had been shown. Pet. App. 3a.

Proceedings below. Petitioner sought treatment with Zyderm in 1987. After her doctor administered a skin sensitivity test, petitioner complained of muscle and joint pains allegedly arising from a condition later diagnosed as dermatomyositis/polymyositis (DM/PM). Pet. App. 3a. Thereupon, petitioner sued Collagen in Massachusetts state court, seeking damages for negligence in the testing, manufacture and sale of Zyderm and for breach of implied warranties of merchantability, and treble damages for sale of personal property by deceit or fraud in violation of Massachusetts law (Mass. Gen. L. ch. 231, § 85J). Pet. App. 22a.

Collagen removed the case to federal court and filed a motion for summary judgment on December 27, 1991,

arguing that petitioner's claims were preempted by federal law, specifically, section 521 of the FD&C Act, 21 U.S.C. § 360k. Section 521 preempts any state requirement relating to safety or effectiveness that is different from, or in addition to, a federal requirement applicable to the device in question. The district court (Mazzone, J.) granted Collagen's motion for summary judgment. Pet. App. 22a-23a.

The court of appeals affirmed, finding that all of petitioner's state-law claims were expressly preempted under section 521. Pet. App. 1a-21a. In his opinion for the court, Judge Torruella analyzed petitioner's claims pursuant to this Court's decision in *Cipollone v. Liggett Group, Inc.*, 112 S. Ct. 2608 (1992). Pet. App. 5a-6a. As required by *Cipollone*, he concluded that section 521 applies to state tort actions, because such actions impose "requirements" within the meaning of the law. *Id.* at 7a-8a.

Judge Torruella noted FDA's view, as expressed in the agency's regulations, that "[a]ny state requirement which, in effect, establishes a new substantive requirement for the device in a regulated area such as labeling, is preempted." Pet. App. 8a. He determined that FDA did in fact impose specific requirements for the labeling and design of Zyderm through the PMA process. *Id.* at 7a-8a.

Judge Torruella then analyzed each of petitioner's claims separately. He determined that petitioner's claims of strict liability, breach of warranty, negligence, misbranding, and failure to warn all were predicated upon the imposition of requirements different from or in addition to those imposed by FDA, and thus that they are expressly preempted by section 521. Pet. App. 8a-11a. He also rejected petitioner's claim of fraud because the Massachusetts statute on which that claim was based requires privity with the seller, and "no privity existed between [petitioner] and Collagen." *Id.* at 11a.

Senior Judges Aldrich and Campbell concurred in a separate opinion. Pet. App. 13a-21a.[1] The concurring judges noted that Congress enacted the preemption statute to encourage research and development in the medical device area, for the purpose of furthering the public health. *Id.* at 14a-15a. Analyzing the language of section 521, they found it to be a "clear demonstration of Congressional choice" in favor of the view that specific FDA requirements represent "the total maximum protection afforded the individual user," rather than "merely the minimum." *Id.* at 16a. They explained that insofar as petitioner's "sustainable claims are premised on a failure to warn, preemption here is unavoidable," *id.* at 18a, because such claims would effectively impose requirements beyond those established by FDA. As to petitioner's remaining claim of fraud, the concurring judges concluded that, to the extent it could be construed as an allegation that FDA itself had been defrauded, the claim amounted to a request that a court or jury determine, impose, and enforce new and different labeling requirements based upon the information Collagen allegedly had suppressed during the premarket approval process; the imposition of such new and different requirements under the guise of state tort law, the judges noted, is expressly barred by section 521. *Id.* at 20a.

REASONS FOR DENYING THE PETITION

The court of appeals' decision is correct and, notwithstanding petitioner's assertions to the contrary, does not conflict with the decisions of this Court or of any other appellate court. The petition therefore should be denied.

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[1] The unusual lineup of judges and opinions—a one-judge opinion for the court, with two judges concurring—makes it difficult to discern what in fact constitutes the views of the court of appeals. The concurring judges agreed with "a good deal" of what is said in Judge Torruella's opinion, but they "approach[ed] this case somewhat differently." Pet. App. 13a. To the extent that the differences in approach might make a difference to the result of some future case, it will be up to the First Circuit to clarify what it considers binding in these opinions.

The application of section 521 of the FD&C Act to approved class III devices such as Zyderm represents a straightforward exercise in express preemption. There can be little doubt that section 521 preempts state tort law actions with respect to class III devices that are subject to premarket approval requirements—every court squarely to address the issue has so held.

Section 521 preempts state requirements that are different from federal requirements. The terms of FDA's premarket approval impose specific federal requirements for labeling and design. State tort actions alleging, in substance, inadequacy in the labeling or design of a device subject to premarket approval thus are preempted.

In arguing that some courts have held otherwise, petitioner relies upon inapposite cases where the medical devices at issue were not class III devices subject to premarket approval; in those cases, no relevant federal requirements triggering preemption had been imposed. But in cases involving class III devices, the courts consistently have read section 521 to preempt state tort claims of the sort made by petitioner here.

Three federal courts of appeals now have so held (all in cases involving petitioner's counsel). Last year, this Court denied certiorari after the Seventh Circuit ruled that section 521 protects manufacturers of class III devices from state tort claims that implicate requirements different from those imposed by FDA. *Slater v. Optical Radiation Corp.*, 961 F.2d 1330, 1333 (7th Cir. 1992), *cert. denied*, No. 92-303 (October 13, 1992). The Fifth Circuit now has joined the Seventh Circuit in *Slater* and the First Circuit here in so ruling. *Stamps v. Collagen Corp.*, 984 F.2d 1416 (5th Cir. 1993), *pet. for cert. pending*, No. 98-1989 (filed June 13, 1993). There is thus a growing unanimity of treatment of this issue in the courts of appeals. There is no reason or need for plenary review of the issue by this Court.

1. When it added section 521 to the FD&C Act as part of the Medical Device Amendments of 1976, Congress expressly preempted competing state requirements:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this Act to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act.

21 U.S.C. § 360k(a). The crux of this case is that petitioner's tort claims would erect "requirements" beyond those specifically established by the FDA, and hence they are preempted.

Petitioner's argument (Pet. 20-24) that the term "requirement" does not encompass state tort claims cannot prevail in light of this Court's decision in *Cipollone v. Liggett Group, Inc.*, 112 S. Ct. 2608 (1992). There, six Members of the Court concluded that similar language in the Public Health Cigarette Smoking Act of 1969 applied to state tort claims. *Id.* at 2619-21 (Stevens, J.); *id.* at 2632-38 (Scalia, J.). Every lower federal court to have addressed the question since *Cipollone* has similarly concluded that preemption statutes applicable to state "requirements" cover common law claims as well as positive enactments. *See, e.g., Arkansas-Platte & Gulf v. Van Waters & Rogers,* 981 F.2d 1177, 1179 (10th Cir. 1993), *pet. for cert. pending,* No. 92-1784 (filed May 10, 1993) (preemption under the Federal Insecticide, Fungicide, and Rodenticide Act); *Papas v. Upjohn Co.*, 985 F.2d 516 (11th Cir. 1993) (same).

Petitioner argues principally (Pet. 12-13) that there are no federal "requirements" applicable to Zyderm that could give rise to preemption under section 521. This

argument, which rests on a fundamental misapprehension of the federal regulatory scheme for class III devices, was extensively considered and rejected below. Pet. App. 2a-3a, 8a-10a, 16a-18a.

Class III devices are subject to the most extensive level of federal regulation, and to the most specific federal requirements governing all aspects of their design and labeling. The manufacturer must submit full information on these and other aspects of the device to FDA before marketing, and commercial distribution can proceed only upon FDA approval of the PMA application.[2] *See* Pet. App. 16a-17a. The approval represents a license to market the product in accordance with the precise conditions specified by FDA to ensure the safety and effectiveness of the device. *See* 21 U.S.C. § 360e. These conditions—which specify how the particular device in question must be manufactured and labeled—are the federal "requirements" that cannot be supplemented by the states under section 521.

To be sure, these requirements are made applicable through the terms of the premarket approval rather than through regulations. But section 521 is not limited to federal requirements imposed by regulations. As FDA itself has explained, state requirements are preempted when FDA "has established specific counterpart regulations *or* there are *other specific requirements* applicable to a *particular device* under the act," 21 C.F.R. § 808.1 (d) (emphasis added), and "[f]or a device classified in class III . . . , the counterpart FDA requirement [is] the requirement that the product have premarket approval," 43 Fed. Reg. 18661, 18664 (May 2, 1978). *See also*

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[2] For example, the manufacturer must submit to FDA "full reports of all information" regarding whether or not the device is safe and effective; a "full statement of the components, ingredients, and properties" of the device; a "full description of the methods used" to manufacture the device; samples of the device, if requested by FDA; the labeling proposed to be used for the device; and any other relevant information required to be submitted by FDA. 21 U.S.C. § 360e(c)(1).

45 Fed. Reg. 67321, 67323 (October 10, 1980) (when FDA establishes a premarket approval requirement for a class III device, state law is preempted).

Both opinions below followed the claim-by-claim preemption analysis established by *Cipollone*. Given the existence of federal labeling and design requirements, it is beyond dispute that petitioner's numerous failure-to-warn and negligent or inadequate design claims are preempted. Pet. App. 8a-11a, 13a-14a, 18a.[3] Petitioner's single remaining claim, relating to alleged fraud, was ill-defined and, procedurally, was not properly presented below.[4] In any event, the court of appeals rejected that claim on state-law grounds (lack of privity). Pet. App. 11a. The concurring judges further explained that petitioner's claim of fraud on patients or physicians was devoid of record support, *id.* at 21a n.8, and that any claim of fraud on FDA itself was simply a disguised attempt to impose state requirements different from those imposed by FDA. *Id.* at 20a.[5] None of these various alternative holdings warrants further review.

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[3] Petitioner's variously stated claims that Zyderm was not accompanied by adequate warnings, and was not properly manufactured or designed, fly in the face of FDA's determination that the product is safe and effective when labeled and manufactured in accordance with the requirements of the PMA approval. Petitioner never alleged that Collagen manufactured or marketed Zyderm in violation of any of those federal requirements.

[4] The district court ruling was based on petitioner's original complaint. The court of appeals did not resolve Collagen's procedural objection that petitioner's amended complaint was not properly on appeal. The court nonetheless addressed the amended complaint, reasoning that it contained only a "few additions" to the original complaint. Pet. App. 3a-4a n.1; *see also id.* at 13a-14a. To the extent that those additions expand petitioner's fraud (and other) claims, Collagen reiterates its objection that the amendment cannot stand because petitioner had represented in the district court that she would withdraw the amended complaint. Collagen also objects to petitioner's belated effort (Pet. 5-6 n.3, 25 n.20) to introduce extra-record evidence to support her fraud claim.

[5] In substance, petitioner's claim was that, in the absence of the alleged fraud, FDA would have imposed different labeling re-

2. The lower courts have consistently held that section 521 expressly preempts state tort claims challenging aspects of a device's design or labeling that are subject to federal requirements. Two other courts of appeals have so held in the only other appellate cases to address the issue involving class III devices. *See Stamps v. Collagen Corp.*, 984 F.2d 1416 (5th Cir. 1993), *pet. for cert. pending*, No. 92-1989 (filed June 13, 1993) (approved class III device); *Slater v. Optical Radiation Corp.*, 961 F.2d 1330 (7th Cir.), *cert. denied*, 113 S. Ct. 327 (1992) (class III device subject to investigational device requirements). Similarly, numerous courts have held that section 521 expressly preempts failure-to-warn claims for class II devices, such as tampons, for which warning requirements have been specified by FDA. *See, e.g., Moore v. Kimberly-Clark Corp.*, 867 F.2d 243, 246 (5th Cir. 1989); *Berger v. Personal Products, Inc.*, 797 P.2d 1148, 1150-51 n.9 (Wash. 1990), *cert. denied*, 111 S. Ct. 1584 (1991) (collecting cases).

There is no conflict. The tampon cases cited by petitioner (Pet. 17) find preemption of warning claims; they do not extend preemption to design claims, but only because there are no specific FDA design requirements applicable to those class II devices. Class III devices subject to premarket approval, such as Zyderm, are subject to FDA design requirements, and thus preemption under section 521 reaches design claims against such devices. *See Stamps v. Collagen Corp., supra*, 984 F.2d at 1421 (Fifth Circuit relied on its own tampon decision in *Moore*

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quirements for the device, and Collagen should be held liable under state law for failing to adhere to those different requirements. But it is the very fact that petitioner is seeking the imposition of different requirements that renders her claim preempted under section 521.

To the extent that petitioner would recast the claim as one resting on alleged violations of federal reporting requirements, it must be rejected because there is no private cause of action under the FD&C Act. Pet. App. 20a; *see also, e.g., Florida ex rel. Broward County v. Eli Lilly & Co.*, 329 F. Supp. 364 (S.D. Fla. 1971).

to find broad preemption of tort claims with respect to class III devices). The hearing aid cases upon which petitioner relies (Pet. 15-16) likewise involved neither class III devices nor state-law claims at odds with FDA requirements.[6] And *Hurley v. Lederle Laboratories*, 863 F.2d 1173 (5th Cir. 1988), which petitioner cites as a conflicting decision with respect to her fraud claim (Pet. 20), did not involve section 521 at all; it involved a vaccine regulated under a different statute, the Biologics Act, 42 U.S.C. § 262, which does not contain a preemption provision.

Petitioner never brought the other purportedly conflicting case she cites (Pet. 13), *Larsen v. Pacesetter Systems, Inc.*, 837 P.2d 1273 (Haw. 1992), to the attention of the court of appeals even though *Larsen* was decided shortly after argument and nearly four months before she filed her petition for rehearing below. In any event, *Larsen* is, at bottom, wholly different; the device there was not subject to any requirements imposed by FDA as part of the class III premarket approval process.[7] As the *Larsen* court itself explained, the notice process at issue in that case " 'is not equivalent to an approval by the FDA of the device's safety and effectiveness.' " 837 P.2d at 1282 (citation omitted). The Fifth Circuit in *Stamps*, in holding that tort claims are preempted with respect

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[6] *See Smith v. Pingree*, 651 F.2d 1021 (5th Cir. Unit B 1981); *New Jersey Guild of Hearing Aid Dispensers v. Long*, 384 A.2d 795 (N.J. 1978). These pre-*Cipollone* cases principally dealt with state requirements governing the fitting and dispensing of hearing aids, as to which there are no federal requirements. *Smith* also upheld a state "disclaimer" provision that used language substantially identical to a counterpart federal requirement and differed only as to where the disclaimer would be provided. *See* 651 F.2d at 1025.

[7] Although a Class III device, the pacemaker at issue in *Larsen* was marketed pursuant to a grandfather provision that allowed pre-1976 devices and any "substantially equivalent" devices to remain on the market, at least until such time as FDA imposes a PMA requirement for that category of devices. 21 U.S.C. §§ 360(k), 360e(b).

to *approved* class III devices, correctly distinguished *Larsen* on this basis. *See* 984 F.2d at 1423 & n.6. *See also* 21 C.F.R. § 801.97 (permission to market in accordance with notification procedure "does not in any way denote official approval of the device"). Finally, the *Larsen* court also recognized that common law claims could be preempted in the event that specific FDA requirements applied to the device in question, and it cited the Seventh Circuit's decision in *Slater* approvingly. *See* 837 P.2d at 1281-82.

3. The decision below also is consistent with FDA regulations interpreting section 521. In the first place, FDA agrees that section 521 preempts state requirements established through court decisions: section 521 reaches "any requirement with respect to a medical device intended for human use having the force and effect of law (whether established by statute, ordinance, regulation, or *court decision*), which is different from, or in addition to, any [federal] requirement applicable to such device . . . ." 21 C.F.R. § 808.1(b) (emphasis added). Moreover, as noted above (pages 8-9), FDA interprets the statutory reference to federal requirements to include those imposed through PMAs, as occurred in this case. Both the court below (Pet. App. 7a) and the court in *Stamps* (984 F.2d at 1421 nn. 1 & 2) concluded that preemption was consistent with FDA's regulations.

In the face of section 521 of the FD&C Act and section 808.1(b) of the regulations, petitioner relies (Pet. 20) on two statements by FDA officials, an advisory opinion and an informal letter, to urge that FDA does not interpret section 521 to preempt state tort actions.[8]

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[8] Petitioner also cites (Pet. 21-22) passages in section 808.1(d) to dispute the clear import of the phrase "court decision" in section 808.1(b), but subsection (d) merely confirms the unremarkable fact that generally applicable requirements such as the Uniform Commercial Code are not preempted. This says nothing, however, about whether those state laws can be applied in a way that imposes substantive requirements on a device that differ from the require-

Neither of these pre-*Cipollone* statements would be entitled to any weight even if they purported to restrict section 521 in the manner suggested by petitioner: the plain statutory language controls, and thus the term "requirements" must be accorded its obvious meaning.

In any event, the two statements by FDA officials are irrelevant to the issue presented here. The advisory opinion was addressed only to the question whether state injunctive remedies may be made available with respect to intrauterine devices "produced, marketed and inserted into women *prior* to the enactment of [section 521]." Pet. App. 25a (emphasis added). The opinion thus has nothing to do with the issue in this case. In particular, the advisory opinion does not purport to clarify the phrase "court decision" as used in 21 C.F.R. § 808.1(b); indeed, the regulation is never even cited in the opinion.

The letter on which petitioner relies (Pet. App. 27a) simply reiterates that general common law standards are not preempted unless directly applied to a device that is subject to FDA requirements. Here, of course, petitioner seeks such a direct application. In any event, such informal correspondence is entitled to no weight to the extent that it would conflict with the clear terms of FDA's regulation. 21 C.F.R. § 10.85(k).[9]

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ments imposed by FDA. As to that fact situation, the regulation makes clear that preemption would apply (§ 808.1(d)(6)(ii)). Moreover, the laundry list in subsection (d) of general requirements that are not preempted does *not* include tort claims, thus confirming that FDA intended those to be treated as among the requirements imposed through "court decision" that are preempted under subsection (b).

[9] Finally, petitioner reads section 521(b) of the Act, which allows states to petition for an exemption from the preemptive effect of section 521(a), as a limitation on the scope of preemption (Pet. 23). Petitioner argues that subsection (b) does not apply to common law claims, and thus that subsection (a) must not either. But this argument is pure bootstrapping. There is nothing in subsection (b) which limits it in the manner petitioner contends. To the contrary, as petitioner concedes, the language of

4. Petitioner incorrectly asserts that the decision below leaves "*all* patients who are injured by Class III medical devices . . . without a remedy." Pet. 11 (emphasis in original). Under section 521, as correctly construed below and in such cases as *Stamps* and *Slater*, plaintiffs are entitled to recover for injuries caused by the violation of federal requirements, such as the conditions established by an applicable PMA or FDA regulation, if such a violation constitutes negligence or is otherwise actionable under state law.[10] And of course section 521 has no application to devices that are not subject to federal requirements or to state claims that do not implicate such requirements.[11]

Beyond those considerations, it should be remembered that, in the eye of the law, a plaintiff is injured not by a device but by a defendant's violation of a legal duty. The central purpose of section 521 is to limit a manufacturer's relevant legal duties in order to encourage the development and marketing of socially beneficial medical devices. *See* Pet. App. 14a-16a. By proscribing the imposition of additional state duties, such as strict liability standards and other state tort doctrines invoked by petitioner, Congress has rejected petitioner's facile equation of physical harm with legal injury. As the concurring

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subsections (a) and (b) "is parallel" (Pet. 23), and as the court of appeals correctly held pursuant to *Cipollone*, subsection (a) applies to common law claims; subsection (b) thus applies to them as well.

[10] In many jurisdictions, violations of FDA requirements may constitute negligence *per se*. *See Stanton v. Astra Pharmaceutical Products, Inc.*, 718 F.2d 553, 565 (3d Cir. 1983) (failure to report adverse drug experiences); *Orthopedic Equipment Co. v. Eutsler*, 276 F.2d 455, 460-61 (4th Cir. 1960) (device misbranding). *Cf. Merrell Dow Pharmaceuticals Inc. v. Thompson*, 478 U.S. 804 (1986) (state tort claims founded on alleged violations of FDA requirements did not present a federal question).

[11] *See Slater, supra*, 961 F.2d at 1334 (medical malpractice claims alleging improper implantation or removal of intraocular lenses would not be preempted).

judges below correctly recognized, "[p]ublic health is a valid federal purpose, and Congress can reasonably weigh possible loss to the idiosyncratic few against benefits to the public generally." *Id.* at 14a-15a.

Accordingly, section 521 means that plaintiffs cannot ask judges and juries to second-guess FDA's safety and utility determinations for medical devices whose labeling and design it has reviewed and approved. That is the decision *expressly* made by Congress, for the purpose of furthering the development of innovative medical technology (Pet. App. 15a-16a); and thus petitioner's invocation of various presumptions guiding *implied* preemption analysis (Pet. 11) is beside the point. *See Cipollone, supra,* 112 S. Ct. at 2620-22 (Stevens, J.).

CONCLUSION

For the foregoing reasons, the petition should be denied.

Respectfully submitted,

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August 1993